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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/634,038

08/08/2000

Gregory S. Keller

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

06/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/634,038

Applicant(s)

KELLER, GREGORY S.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication; even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election of Species A and Species BB in the reply filed on 4-2-07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Although Examiner agree claim 1 is generic, the presence or not of a generic claim fails to provide grounds for arguing the basis of the restriction requirement.

Claims 5 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5-2-07.

Response to Amendment

1. Applicant's arguments with respect to claims 1-4,6-8,10-11 have been considered but are not persuasive.
2. With regard to claims 1-4,8, and 11, Examiner maintains the position set forth in the prior office action mailed 5-18-06 at page 2, paragraph 2.
3. Regarding claims 1,2,5 ('001 or '025 in view of '138), Examiner maintains the position set forth in the prior office action mailed 5-18-06 at page 3, paragraph 3. Applicant requests further explanation regarding the Examiner's position that column 1, lines 22-24 of Agerup: "Materials used for augmentation of tissues are, for instance, the patients own fat cell cartilage, or other materials." would be interpreted by one of ordinary skill in the art of tissue augmentation to mean "the patient's own fat cell, cartilage, or other materials". Applicant suggests "*one skilled in the art would be more likely to consider the term "fat cell cartilage" to*

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refer to some fat cell component" (lines 13-14, page 8). Examiner disagree because "fat cell cartilage" does not exist. Fat cells and cartilage are completely different in structure. Fat cells do not have cartilage. One of ordinary skill in the art of tissue augmentation would know cartilage tissue or fat cells are commonly used injectable materials for tissue augmentation.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4,8,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073.

Boss Jr discloses in line 22 of col. 3 through line 37 of col. 6 a method of corrective surgery comprising the steps of obtaining dermal fibroblast cells from the patient, culturing the cells in vitro, and implanting the cells by injection. Boss Jr discloses example applications of the method such as depressed scars and wrinkles, but not expressly for vocal cord and furthermore lacks the express disclosure of including a phosphate buffered solution. Daniels et al. teaches a method of corrective surgery in lines 17 of col. 2 through line 59 of col. 5 for depressed scars and wrinkles as well as vocal cord defects. Furthermore, Daniels et al. discloses a rinsing step utilizing a phosphate buffered saline solution to rinse cells.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Boss Jr by utilizing a phosphate buffered solution to rinse the cells and apply the method to tissue of the vocal cord to correct vocal cord defects as taught by Daniels et al. in order to treat a vocal cord.

3. Claims 1,2,5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agerup US PN 5,633,001 or Hubbard US PN 5,922,025 in view of Vacanti US PN 5,041,138.

Each of Agerup (lines 8-28 of col. 1) and Hubbard (line 52 of col. 3 through line 3 of col. 4) disclose a method of repairing a vocal cord defect by autologous cell injections. Agerup and Hubbard both lack the express written disclosure of culturing the cells in vitro before injection. Vacanti et al. teaches in abstract culturing cells in vitro before implantation in order to ensure adequate cell volume and density for the cells to survive in vivo.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Agerup or Hubbard by culturing the cells in vitro before implantation as taught by Vacanti et al. in order to ensure adequate cell volume and density for the cells to survive in vivo.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073 as applied to claim 1 above, and in further view of Osbourne et al. US ub 2004/0156833.

The method disclosed by Boss Jr. as modified by Daniels et al. meets the limitations of claim 10 as described above, and discloses using bovine serum but lacks the express written

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disclosure of using the patient's serum for culture medium. Osbourne et al. teaches in paragraph [0009] that it is well known in the art to use a patient's own serum for culturing cells for implantation to ensure biocompatibility of the implanted cells.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Boss Jr, as modified by Daniels et al., to include culturing the cells in the patient's own serum before implantation to ensure biocompatibility of the implanted cells.

Allowable Subject Matter

5. Claims 6,7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

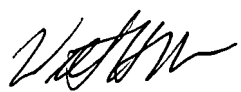
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


WILLIAM H. MATTHEWS
PRIMARY EXAMINER
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